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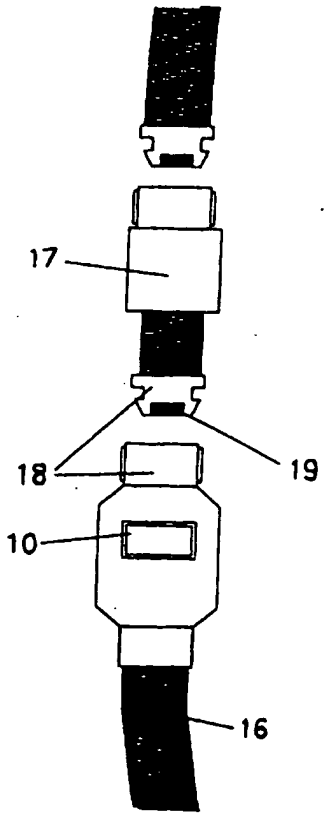
(54) Title: A PERSONAL DEVICE FOR MONITORING VITAL FUNCTIONS

(57) Abstract

The invention relates to a personal ambulatory apparatus for monitoring vital functions of the person carrying it, comprising one or more probes adapted to non-invasive monitoring of vital functions. The invention is characterized in that the apparatus comprises an oximeter, a data processing unit, and a storage and a separate power supply and that all above components are placed in the same casing or on the same suspension strap (16). According to a suitable embodiment the oximeter is based on the measurement of light reflected from the hypodermic tissue (11).



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A PERSONAL DEVICE FOR MONITORING VITAL FUNCTIONS

The invention relates to a portable or ambulatory apparatus for personal use which non-invasively monitors and measures the vital functions of the person carrying it.

Prior art level

Various kinds of apparatuses have been developed for monitoring human vital functions. Most of these are models designed for hospital environment confining the patient to the bed or at least to the immediate vicinity of the non-portable apparatus. Monitoring apparatuses designed for ambulatory use have also been developed, examples of which we cite the following patent publications.

The publication WO 93/16636 depicts an apparatus connected to a wrist strap comprising probes for measuring among other things temperature and conductivity of the skin as well as motion. The apparatus further comprises a radio transmitter whereby, if need be, an alarm can be transmitted to a separate receiver.

The wrist apparatus depicted in the publication WO 90/00366 measures only pulse detected by ultrasonic measurement of blood flow rate. Furthermore, it is stated that other measurements may also be incorporated with the apparatus.

However, these patent applications do not mention an oximeter i.e. a device for measuring oxygen saturation of blood. This is an obvious drawback because in certain cases continuous measurement of oxygen saturation of blood is particularly important in diagnosis or in the

monitoring of the patient's health.

Patent publication US 5,275,159 describes a portable apparatus for the diagnosis of sleep apnea for monitoring the patient's heart rate and oxygen saturation of blood. The oximeter employed herein is of a conventional type which is based on the measurement of light passing through the finger. However, owing to the oximeter solution as well as the solution of other components this apparatus in its entirety considerably restricts the normal life of the person being monitored. For this reason it cannot be considered as an actual easy-to-use ambulatory apparatus.

Benefits and problems of present oximeter solutions

In conventional oximeters based on the measurement of light passing through tissue, probes must be placed at such positions where transillumination is possible e.g. at the auricle or the finger tip. These places are not practical in prolonged monitoring of an ambulant patient although the above positions give high signal amplitude due to strong circulation. The reflection-type oximeter has an advantage in that the probe can in principle be placed freely although there remains the problem that the density of the capillary system of the skin varies considerably in different parts of the body. Furthermore, the portion of incident light that reflects from the tissue is five times less than the portion of the incident light that passes through the finger or the auricle and it has also been a problem to attach the probe sufficiently well to the patient.

Due to the above problems, finger oximeter is used only for monitoring the vital functions of an immobile or slightly ambulant patient like patients being operated or under intensive care. Use of reflection-type oximeters

have not become common and only a few commercial models are available which measure within the region of dense capillary system limiting the possible measuring region to the face.

Modern oximeters designed for continuous monitoring have invariably a separate probe which is connected with a wire to a separate and often mains-operated data processing and storage unit.

The objective of the invention

The objective of this invention is to enable such a continuous monitoring of oxygen content of blood that does not prevent the normal life of the subject. And furthermore to obtain a new and versatile apparatus for ambulatory monitoring of vital functions which can be easily furnished with new properties and which does not have the limitations of prior art apparatuses.

The characteristic features of the invention appear from claim 1.

General description of the apparatus according to the invention

The apparatus according to the invention predominantly measures oxygen saturation and pulse and optionally other vital functions of the person carrying it. Besides the measuring probes the apparatus is provided with a storage, data processing unit and a separate power supply. The apparatus may further be provided with a display, alarm and/or a data communications gate. The apparatus can be secured to its carrier with a strap and it can be held, for example, on the wrist or on the chest. It is possible to attach one or more accessory units in succession to the

suspension strap in connection with the main apparatus. In specific applications, the functions of the main apparatus may be distributed all over the suspension strap. The data in storage may be retrieved to the microcomputer for closer analysis. This enables a prolonged registering of vital functions of the person. The apparatus may be connected to a wireless long-distance alarm system.

A detailed technical description of the apparatus according to the invention

The invention will be explained in the following referring to the enclosed drawings in which

Fig. 1 shows schematically the basic functions of the apparatus according to the invention,

Fig. 2 shows the measuring principle of the oximeter employed in the apparatus according to the invention,

Fig. 3 shows the apparatus according to the invention secured to a suspension strap with an attached accessory unit,

Fig. 4 shows that side of the apparatus according to the invention which is placed against the skin and its oxygen saturation probe according to one embodiment.

In Fig. 1, which shows schematically components of the apparatus according to one embodiment of the invention, is shown on the left an oximeter probe 1, temperature probes 2 as well as other optional probes 3. Measuring signals are converted to digital form with an A/D converter 4. A data processing unit 5 receives, compares, and analyzes

measured data from the probes, and monitors for possible exceeding of given alarm limits and actuates, if necessary, an alarm 6. The apparatus stores the measuring data in storage 7 in chronological order. The stored data are coded and compressed for saving storing capacity. Measuring and data processing operations are performed at specific intervals for minimizing power consumption. A timer 8 of the apparatus controls the operational cycle of the apparatus. Connections to possible accessory units as well as data transfer between the measuring instrument and the PC are taken care via the data communications bus 9. Measuring results and causes of alarms can be read from a display 10.

Fig. 2 shows the measuring principle of the oximeter employed in the apparatus of the invention. This type of probe is based on the measurement of changes of light reflected from blood vessels 12 of the hypodermic tissue 11. A light source 13 contains components necessary for emitting two or more separate wavelengths. In this solution, the light source 13 and the receiver 14 may be situated on the surface 15 of the skin on the same side of the tissue which is measured. Thus it is possible to place the entire apparatus with its probes e.g. on the wrist or the chest and it may be secured to the patient by a strap. This makes it possible to accomplish a portable and an oximeter-based monitor of vital functions so that monitoring does not restrict normal life of the patient because using the apparatus is not significantly different from using a wrist watch.

Fig. 3 shows an apparatus according to the invention provided with a display 10 and secured to a suspension strap 16 with an accessory unit 17 attached thereto. A data communications gate 19 is disposed to the fastening mechanism 18 of the strap. The fastening mechanism may

also function as the actuating switch of the apparatus.

Fig. 4 shows that side of the apparatus of the invention which is placed against the skin and the structure of the oximeter probe according to one embodiment of the invention. The light source 13 and the receiver 14 are located in a bulge 21 at the bottom 20 of the casing of the apparatus. In this way the probe is made to press with a slight pressing force (causing no inconvenience to the patient) tightly against the skin. Pressing increases the signal amplitude because it diminishes the portion of the venous blood, which has a lower pressure than artery blood, in the measuring area, which would otherwise hinder the measurement. A corresponding probe could be accomplished by employing an optical fibre and then the transmitter and the receiver can be placed inside the apparatus and only the ends of the optical fibres are in the bulge.

Measurement of oxygen saturation and pulse

Oxygen saturation of blood is measured optically on the pulse oximeter principle in which light of two wavelengths (red and infrared) is sent in succession into the tissue. A plethysmographic pulse curve is observed using both wavelengths and a sufficiently sensitive probe from the intensity change of either the light that passed through the tissue or the light that was reflected therefrom. Oxygen saturation of blood can be calculated from the ratio of the amplitudes of the pulse curve and the so-called DC levels of the curves. Saturation can also be estimated when the pulse is not observed but then the measuring result does not tell the absolute value of the oxygen saturation of the blood but only changes in the saturation.

Although the oximeter based on the measurement of reflected light is known per se, literature does not propose its use in ambulatory apparatuses according to this invention. Furthermore, the physical structure of the oximeter probe, which is described in Fig. 4 and in its caption, is not known in prior art, neither is the use of measurements, which will be mentioned later, incorporated with the oximeter measurement for reliability assessment of the oximeter results.

One or more of the following measurements may be added to the apparatus according to the invention, either fixedly to the instrument casing or to the suspension strap or to the accessory unit connected thereto.

Measurement of temperature

Measurement is accomplished with two thermistors, one of which measures the ambient temperature and the other the surface temperature of the skin. Further, from the knowledge of the amount of heat the apparatus itself generates and the thermal conductivity one can estimate the true body temperature. In assessing the temperature one must take into account the position of the apparatus on the body. Temperature information may also be utilized in reliability assessment of the oximeter results.

Motor activity and posture of the body

Motor activity and posture of the body can be measured with mercury switches placed crosswise or with accelerometers. Motion sensitive probes may be connected to a sum counter in order to use the information they provide in the determination of motor activity so that the data processing unit need not continuously follow the state of the switches. Reliability of the oximeter results

can also be assessed on the basis of the measured motor activity.

An electret membrane, which reacts to changes in pressure and position, may also be placed to the suspension strap. If the apparatus is attached, for example, on the chest, it is possible to measure from the voltage changes induced by forces exerting on the membrane, among other things, mechanical functioning of the heart, breathing motions, and motor activity.

A signal obtained from the oximeter probe may also be used for the determination of motor activity in which signal the motions manifest as disturbances. From the strength of said signal it can be also assessed whether the apparatus has been placed so as the measurement situation requires.

Other measurements

As distinct from the foregoing the measurements presented in the following, which may be optionally incorporated with the apparatus, have no embodiments distinct from prior art.

It is possible to incorporate also other measurements like EKG with the apparatus which can be accomplished without any probes distinct from the entirety of the apparatus. Furthermore, it is possible measure ambient factors like gas concentrations, sound and illumination.

It is obvious to the specialist in the field that various embodiments of the invention may vary within the limits of the enclosed claims.

CLAIMS

1. Personal ambulatory apparatus for monitoring vital functions of the person carrying it, comprising one or more probes adapted to non-invasive measurement of vital functions characterized in that the apparatus comprises an oximeter, a data processing unit (5), a storage (7) and a separate power supply and that the above components are placed in the same casing or on the same suspension strap (16).

2. Apparatus according to claim 1 characterized in that the oximeter is based on the measurement of light reflected from hypodermic tissue (11).

3. Apparatus according to claim 1 or 2 characterized in that the transmitter (13) and the receiver (14) of the oximeter probe or the light transmitting components associated therewith are placed in a bulge (21) pressing against the skin.

4. Apparatus according to claim 1, 2 or 3 characterized in that it comprises a timer (8) enabling control of the operating cycle of the apparatus.

5. Apparatus according to any of the claims 1 - 4 characterized in that it comprises components for the measurement of motor activity and/or temperature which enable the apparatus to check the operation of the oximeter.

6. Apparatus according to any of the claims 1 - 5 characterized in that it is provided with a display (10), data communications gate (19) and/or one or more alarms (6).

7. Apparatus according to any of the claims 1 - 6 characterized in that it comprises motion sensitive switches connected to a sum counter and/or an electret membrane sensitive to changes of pressure and position attached to the suspension strap (16) for the determination of motion.

8. Apparatus according to any of the claims 1 - 7 characterized in that it comprises components for comparing the ratio of the surface temperature of the skin and the external temperature.

9. Apparatus according to any of the claims 1 - 8 characterized in that its suspension strap (16) incorporates a data communications bus (9) to which one or more accessory units (17) can be connected.

10. Apparatus according to any of the claims 1 - 9 characterized in that it comprises one or more probes connectable to the same instrument casing and/or to its suspension strap (16) for monitoring other vital functions and/or external factors.

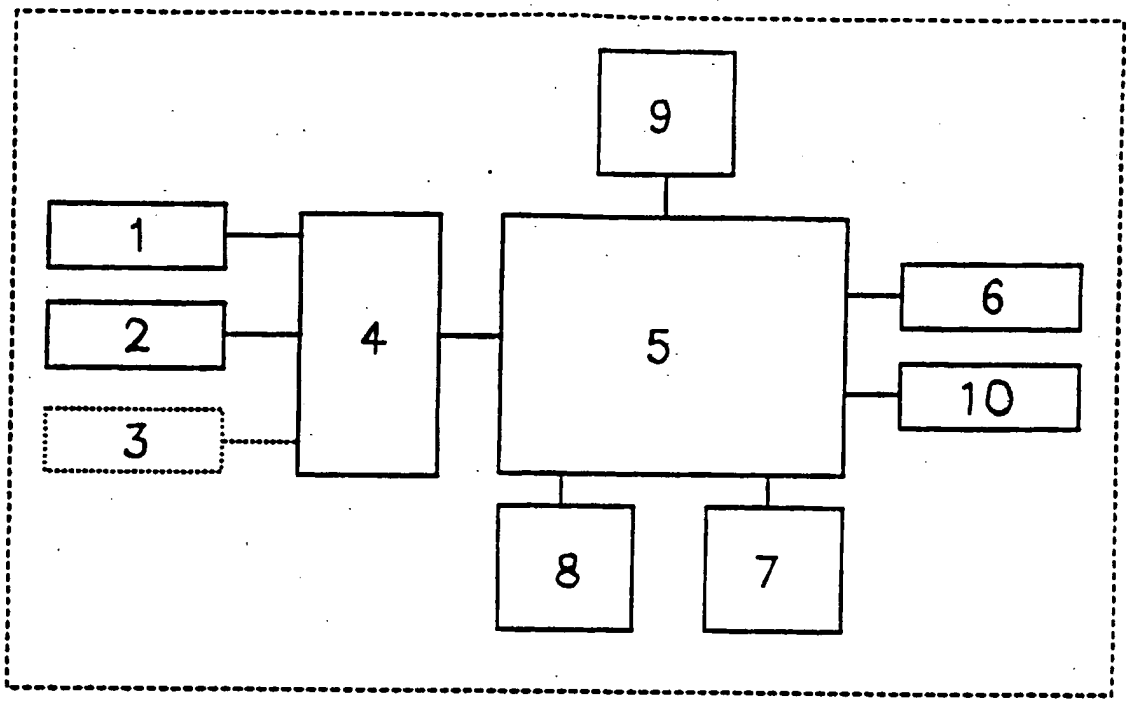

Fig.1

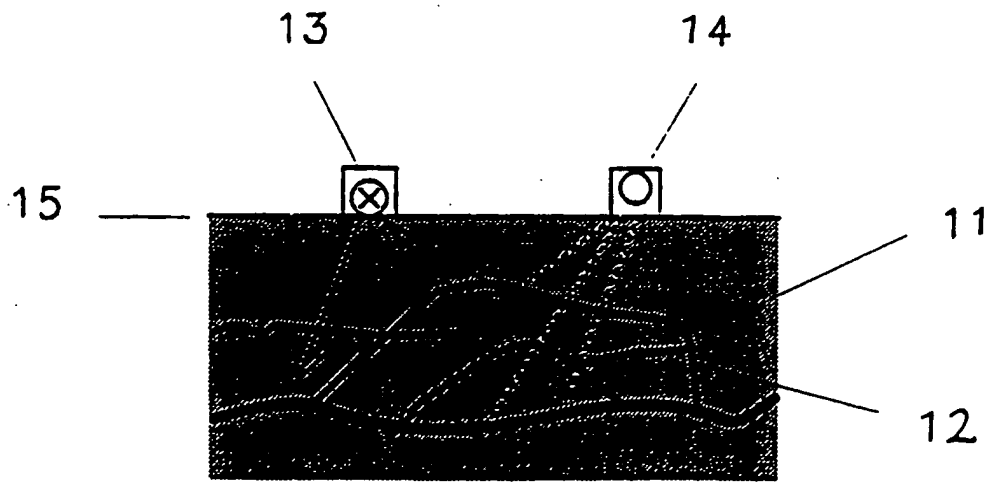

Fig. 2

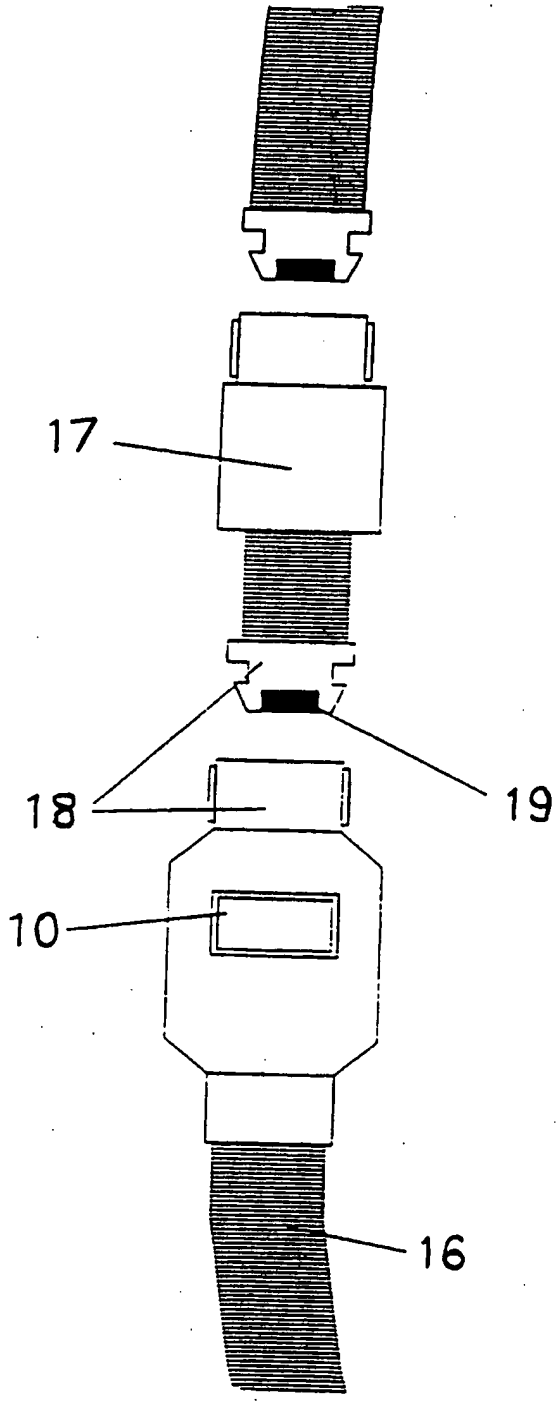

Fig. 3

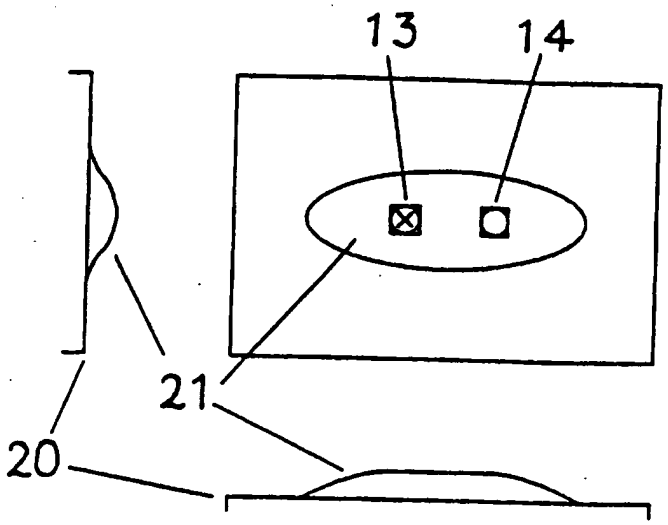

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 95/00652

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5253646 A (DELPY ET AL), 19 October 1993 (19.10.93)	1-9
Y		10
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X	US 5309908 A (FRIEDMAN ET AL), 10 May 1994 (10.05.94)	1-9
Y		10
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X	EP 0444934 A1 (HEWLETT-PACKARD COMPANY), 4 Sept 1991 (04.09.91)	1-9
Y		10
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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1 March 1996	20 -03- 1996
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US 4202350 A (WALTON), 13 May 1980 (13.05.80)	10
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INTERNATIONAL SEARCH REPORT

Information on patent family members

05/02/96

International application No.
PCT/FI 95/00652

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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